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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,562	01/23/2004	Gil M. Vardi	1001.2273105	3207

28075 7590 06/02/2009
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EXAMINER

SWEET, THOMAS

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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06/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/762,562
Filing Date: January 23, 2004
Appellant(s): VARDI ET AL.

J. Scot Wickhem
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03/10/2009 appealing from the Office action mailed 07/01/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5749825	Fischell et al	5-1998
6165195	Wilson et al	12-2000

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(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al (US 6165195) in view of Fischell et al (US 5749825). Wilson et al discloses a method of positioning a main stent in a main vessel at a vessel bifurcation such that a side opening in the main stent is positioned at the an ostium of a branch vessel, the method comprising:

positioning a main guidewire in the main vessel such that a distal end of the main guidewire extends past the vessel bifurcation (fig. 13A);

advancing a stent delivery system over the main guidewire to a position proximate the bifurcation (fig. 13A), the stent delivery system comprising a catheter with a flexible side sheath (55B) attached thereto, wherein the catheter (50) is received over the main guidewire, and wherein the main stent (20) is positioned over the catheter (50) with the flexible side sheath (55B) positioned to pass through the an interior of the main stent and out of the side opening in the main stent (as see in fig. 13D),

subsequently, advancing a branch guidewire (56B) through the flexible side sheath attached to the catheter and into the branch vessel (fig. 13 B);

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subsequently, advancing the catheter over the main guidewire while advancing the flexible side sheath over the branch guidewire (fig. 13C), while-viewing relative movement of a marker positioned on the of the flexible side sheath (the stent and wire are radiopaque, and as described col 17-18 lines 64-14) with respect to at least one marker positioned on the catheter (the stent) when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating the a relative position of the side opening of the main stent with respect to the ostium of the branch vessel.

However, Wilson et al does not disclose the flexible side sheath having a distal end portion extending distal of the side opening of the stent; and that wherein the distal end portion of the flexible side sheath advances into the branch vessel; and while viewing relative movement of a marker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire.

Fischell et al discloses another method of positioning a main stent in a bifurcation including the flexible side (24) sheath having a distal end portion extending distal of the side opening of the stent (as shown in fig 1) for the purpose of helping assure proper longitudinal placement (abs). Thought Wilson et al does not specifically disclose a marker positioned on the distal end portion of the flexible side sheath. The teachings of Wilson et al (col 17-18 lines 64-14) to place markers on components for the purpose of assisting in proper alignment would lead one of ordinary skill in the art to add a distal end marker to the sheath in order to assist in proper alignment. It would have been obvious to one of ordinary skill in the art at the time the invention

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was made to modify the flexible side of Wilson et al to extend the sheath to have a distal end portion extending distal of the side opening of the stent as taught by Fischell et al in order to help assure proper longitudinal placement and to include a distal end marker on the modified flexible sheath to further assist in proper alignment. These modifications would utilize the steps as claimed.

(10) Response to Argument

With regard to the arguments on Fischell et al (page 12), In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant is not stating facts and is entering into conjecture.

Wilson et al has a flexible side sheath that extends from the side opening as seen in fig. 12L it just doesn't clearly fulfill extending far enough to advance into the branch vessel during catheter advancement. Fischell et al has a long flexible side sheath that clearly extends into the branch vessel prior to inflation.

With regard to “viewing relative movement of a marker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter”, Wilson et al discloses viewing the relative movement of parts using radiopaque markings (col 17-18 lines 64-14). “In order to assist in properly aligning both proximal angled stent 10 and main-vessel stent 20 in side-branch vessel 5 and main-vessel 6, respectively, positioning guide wire lumen 39A, on side-branch catheter 31, and guide wire lumen 55A, on main-vessel catheter 50, can be radiopaque, or have a radiopaque marker associated therewith so that they are visible

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under fluoroscopy. Thus, when advancing side-branch catheter 31 and main-vessel catheter 50, the proper orientation can be more easily determined by viewing the position of positioning guide wire lumen 39A in connection with main-vessel 6 or positioning guide wire lumen 55A in connection with aligning aperture 25 with side-branch vessel 5.”. Applicant is relying on the “or” statement to say only one member is viewed during placement. However, the underline statement lists several members having radiopaque markings (including 55A the lumen of the side sheath), the drawing show radiopaque coil tipped guide wires and contrast medium is inherently used in the vessel to see the vessel. Applicant is suggesting each of the other markers visible under fluoroscopy is ignored during placement (So why include the markings?). Extending the flexible side sheath using the teachings of Fischell et al including the lumen 55A having radiopaque marking is in the spirit of Wilson et al (especially since the lumen is disclosed as being marked).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Thomas J Sweet/

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TC 3700 RQAS

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